

K 053196

DEC 16 2005

510(k) Summary  
(As required by 21 C.F.R. §807.92)

Submitted by:	James Delaney Inverness Medical Innovations, Inc. 51 Sawyer Rd., Ste. 200 Waltham, MA 02453
Prepared on:	December 14, 2005
Device name	The Ischemia Albumin Cobalt Binding Test (ACB® Test)
Common name Classification name	Albumin Cobalt Binding Test, Class II, ProCode NJV, Regulation Number § 862.1215.
Predicate Device	Albumin Cobalt Binding Test (ACB® Test)
Modifications	Expanded the models of clinical analysers for assay use with corresponding labeling changes.
Intended Use	<p>The Ischemia Albumin Cobalt Binding Test (ACB®) is quantitative in vitro diagnostic test used on human serum that detects Ischemia Modified Albumin (IMA™) by measuring the cobalt binding capacity of albumin in human serum. IMA is intended for use in conjunction with ECG and cardiac troponin as an aid to the short term risk stratification of patients presenting with chest pain suggestive of cardiac origin.</p> <p>Thus, in patients with chest pain or equivalent symptoms suggestive of cardiac origin, with non-diagnostic ECG and normal troponin, a negative IMA can be used as an aid to rule out Acute Coronary Syndrome (ACS) in low risk patients.</p>
Technological Characteristics	<p>The Ischemia ACB® Test measures the cobalt binding capacity of albumin in a serum specimen. Cobalt is added to serum and allowed to react. Dithiothreitol (DTT), a colorimetric indicator, is added to the reacted specimen and the degree of color formation is detected spectrophotometrically on clinical chemistry analyzers.</p> <p>In normal patients, cobalt binds at the N-terminus of albumin leaving little cobalt to react with DTT and form a colored product. In serum of patients with ischemia, cobalt does not bind to the metal binding sites leaving more free cobalt to react with DTT and form a darker color.</p>
Testing	The following verification/validation testing was done for the additional analyzer: Typical Calibration Curve, Linearity, Sensitivity, Precision, Test Method Comparison, On Board Component Stability, Specificity, and Interfering Substances.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. James M. Delaney  
Director Regulatory Affairs  
Inverness Medical Innovations, Inc.  
51 Sawyer Rd., Ste. 200  
Waltham, MA 02453

DEC 16 2005

Re: k053196  
Trade/Device Name: The Ischemia Albumin Cobalt Binding Test (ACB®)  
Regulation Number: 21 CFR 862.1215  
Regulation Name: Creatine phosphokinase/creatine kinase or isoenzymes test system  
Regulatory Class: Class II  
Product Code: NJV  
Dated: November 15, 2005  
Received: November 16, 2005

Dear Mr. Delaney:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please note that the limitations cited in the substantial equivalent letter for k023834, Albumin Cobalt Binding Test (ACB®) Test, still applies to this device. Therefore the limitation must appear in the Warnings section of the device's labeling.

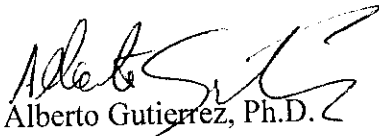
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 240-0443. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Alberto Gutierrez, Ph.D.

Director

Division of Chemistry and Toxicology

Office of In Vitro Diagnostic Device

Evaluation and Safety

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number: K053196

Device Name: The Ischemia Albumin Cobalt Binding Test (ACB®)

Indications For Use: The Ischemia Albumin Cobalt Binding Test (ACB®) is a quantitative in vitro diagnostic test used on human serum that detects Ischemia Modified Albumin (IMA™) by measuring the cobalt binding capacity of albumin in human serum. IMA is intended for use in conjunction with ECG and cardiac troponin as an aid to the short term risk stratification of patients presenting with chest pain suggestive of cardiac origin.

Thus, in patients with chest pain or equivalent symptoms suggestive of cardiac origin, with non-diagnostic ECG and normal troponin, a negative IMA can be used as an aid to rule out Acute Coronary Syndrome (ACS) in low risk patients.

The safety and effectiveness of this device for use in patients with potential Acute Coronary Syndrome (ACS) who have positive IMA levels; or positive troponin levels combined with negative, non-diagnostic or positive ECG; or positive ECG combined with positive or normal troponin levels has not been established. IMA results do not correlate with disease risk in the event of a positive IMA, ECG, or troponin test result, therefore reliance on the IMA results alone could be misleading as either ruling in or ruling out ACS.

Prescription Use  X   
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division of 

Office of   
Device Evaluation

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